Dear HCP,

Urgent Field Safety Notice

Commercial name of the affected product: Nova T 200
FSCA-identifier: PQSC-758
Type of action: recall of several batches from the market
Date: 22 December 2015

Attention:

Affected devices:
Nova T 200 copper IUD (intrauterine device)
Batches:

Impacted Batch No.
TUO0V5S
TUOOV6Z
TUOOVBE
TUOOWGS
TUOOXVN
TUOOXVS
TUO1 OXV
TUO1 1W6
TUO1 1 W7
TUO1 3TA
TU014GU
TU014KP
TU0164J

Bayer Middle East
(Branch)

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1. Description:
Please be informed about a voluntary recall of specific batches of Nova T copper IUD (T-shaped Copper IUD model with 200 mm2 copper surface) by Bayer.
An increased device breakage rate for Nova T 200 IUD was observed. The breakage was noticed during insertion or shortly after insertion in connection with expulsion of the T-body loop with attached threads.
The root cause investigation showed that the increased breakage rate can be traced back to a change in the T-body mold (due to a supplier change) in combination with the use of a specific raw material batch. This caused

a weakness in the T-body of Nova T 200 above the loop to which the removal threads are attached. It leads to an increased risk for breakage when the T-body is bent sideways, or when the strings are pulled at an angle.
The mechanism of breakage identified during the investigations, **and the typical pattern of breakage observed in the cases reported to date indicate that the increased** risk of breakage is linked to the insertion (possible bending force when pushing the T-body out of the insertion tube).
Based on the currently available data and nature of the breakage, no impact on the efficacy of Nova T 200 is expected.
Other IUDs by Bayer (e.g. Mirena, Jaydess, Nova T 380) are not affected by the detected defect as described above.
The stocks of the affected Nova T 200 batches are blocked by Bayer. The affected batches are recalled from all distribution channels by Bayer, the affected batches shall be sent back to Bayer affiliates.

2. Advice on Action to be taken:

Further insertion of IUDs of the affected batches should not be performed.

The removal of an already successfully inserted IUD in absence of any symptom or any other reason for removal is not considered justified in view of the potential risk associated with an additional removal and insertion of a new IUD.

Planned removals of Nova T 200 should be performed by grasping the removal threads with a forceps and applying gentle traction, as per routine procedure.

3. Address to which the affected product shall be returned:
Establishment AlKamal Import Office
Address PO BOX 405 AiJazeera Street AlHamra, Beside united Doctors Hospital, Jeddah Saudi Arabia

4. Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred to.
Please transfer this notice to other organisations on which this action has an impact.
Please maintain awareness of this notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action.